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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,344	01/26/2005	Dominique Swinnen	255452US0PCT	6094

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EXAMINER	
MABRY, JOHN	
ART UNIT	**PAPER NUMBER**
1625	

NOTIFICATION DATE	DELIVERY MODE
01/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/501,344	SWINNEN ET AL.	
	Examiner	Art Unit	
	John Mabry, PhD	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 26-41* is/are pending in the application.

4a) Of the above claim(s) *30-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/10/06 & 10/05/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner's Response

Applicant's response on December 17, 2007 filed in response to the Election/Restriction dated November 16, 2007 has been received and duly noted. The Examiner acknowledges Applicants' election of Group VIII with traverse. The Examiner was not persuaded in view of Applicant's traversal that the groups of Election/Restriction were not distinct and there was not a burden on Examiner to examine the unrestricted claims. The Examiner respectfully refers Applicant to bottom of page 12 and top of page 13 of the Election/Restriction requirement in reference to the burden in absence of this restriction would present to the Examiner (in particular letters (a)-(e) on said pages). Additonally, the Examiner asserts that the unity of invention was properly broken and that each of the restricted groups are patentably distinct. The Examiner has searched elected group VIII and has expanded the restricted to include R1 being an A wherein A includes phenyl or naphthyl. In view of this response, the status of the rejections/objections of record is as follows:

This restriction is made **FINAL**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "derivative" and "substituted" in respective claims are relative terms which renders the claim indefinite. The terms "derivative" and "substituted" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The Oxford Dictionary of Chemistry defines the term derivative as a compound that is derived from some other compound and usually maintains its general structure.

Additionally, the term "substituted" is a relative term which renders the claim indefinite. The term "substituted" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "substituted" and "derivative" have no clear limitations.

For example, it is unclear to the Examiner what specifically the Applicant means by the term "substituted". Please read excerpt from Specification below (see page 12).

Cy is a substituted or unsubstituted aryl, a substituted or unsubstituted heteroaryl, a substituted or unsubstituted (3-8-membered)cycloalkyl or heterocycloalkyl.

More specifically, Cy may be substituted or unsubstituted thienyl, substituted or unsubstituted phenyl which may be substituted by substituted or unsubstituted aryl or substituted or unsubstituted heteroaryl, e.g. an oxadiazole, or substituted or unsubstituted cycloalkyl moiety, or Cy is substituted or unsubstituted thienyl, substituted or unsubstituted phenyl which may be substituted by 1 or 2 moieties selected from the group consisting of NH-CO-R^3, -SO_2-$NR^3R^{3'}$ or –CO-$NR^3R^{3'}$ in which R^3, $R^{3'}$ are independently selected from H, substituted or unsubstituted (C_1-C_{15})alkyl, substituted or unsubstituted (C_2-C_{12})alkenyl, substituted or unsubstituted (C_2-C_{12})alkynyl, substituted or unsubstituted aryl, substituted or unsubstituted heteroaryl, substituted or unsubstituted (3-8-membered)cycloalkyl or substituted or unsubstituted heterocycloalkyl, substituted or unsubstituted (C_1-C_{12})alkyl aryl or heteroaryl, substituted or unsubstituted (C_2-C_{12})alkenyl-aryl or -heteroaryl, substituted or unsubstituted (C_2-C_{12})alkynyl-aryl or -heteroaryl.

What does Applicant intend by the term substituted?

Claims 28 and 29 contains the trademark/tradenames:

supplementary drug selected from the group consisting of insulin, aldose reductase inhibitors, alpha-glucosidase inhibitors, sulfonyl urea agents, biguanides , thiazolidines, PPARs agonists, c-Jun Kinase or GSK-3 inhibitors.

Minalrestat, Tolrestat, Sorbinil, Methosorbinil,

Zopolrestat, Epalrestat, Zenarestat, Imirestat, Ponalrestat, ONO-2235, GP-1447, CT-112, BAL-ARI 8, AD-5467, ZD5522, M-16209, NZ-314, M-79175, SPR-210, ADN 138, or SNK-860, Miglitol, Acarbose, Glipizide, Glyburide, Chlorpropamide, Tolbutamide, Tolazamide, or Glimepriride.

Where a trademark or tradename is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 USC 112, second paragraph. (see Ex parte Simpson, 218 USPQ 1-20 (Bd. Appl 1982). The claim scope is uncertain since the trademark or tradename is used to identify a source of goods, but not the goods themselves. Thus, a trademark or tradename does not identify or describe the goods associated with the trademark or tradename.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 29 is rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey one of ordinary skill in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The expressions

rapid

acting insulin, an intermediate acting insulin, a long acting insulin, a combination of intermediate and rapid acting insulins,

do not convey to one of ordinary skill in the art that Applicants were in possession of the claimed subject matter. The functional language recited without any examples in the Specification. The aforementioned phrase is unduly functional. Names, structures, and chemical formulas precisely define organic molecules. Attempting to define structure by function is not proper when the structures can be clearly expressed in terms that are more precise. It is not sufficient to define a chemical structure solely by its principal biological property. Applicants are attempting to define the structure of a claimed molecule by a single property. The U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences held *in Ex parte Pulvari* 157 USPQ 169 that "a material defined, as here, solely in terms of what it can do, of a property thereof or of the scientific principle that underlies that property ... does [not] particularly point out, as required by the 35 U.S.C. 112, appellant's disclosed invention".

Claims 1-18 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Cy and A (both phenyl) being substituted by: cyano, halogen,

methoxy, hydroxy, phenoxy, -NO_2, trifluoromethyl, Cy is a phenyl or biphenyl being substituted by -SO_2R^3, -CO-$NR^3R^{3'}$ in which $R^{3'}$ is H and R^3 is (C_7-C_{15})alkyl, particularly (C_8-C_{15})alkyl and more particularly a dodecyl group.

not reasonably provide enablement for Cy and A that are substituted by the following:

"Substituted or unsubstituted": Unless otherwise constrained by the definition of the individual substituent, the above set out groups, like "alkyl", "alkenyl", "alkynyl", "aryl" and "heteroaryl" etc. groups can optionally be substituted with from 1 to 5 substituents selected from the group consisting of "C_1-C_6-alkyl", "C_2-C_6-alkenyl", "C_2-C_6-alkynyl", "cycloalkyl", "heterocycloalkyl", "C_1-C_6-alkyl aryl", "C_1-C_6-alkyl heteroaryl", "C_1-C_6-alkyl cycloalkyl", "C_1-C_6-alkyl heterocycloalkyl", "amino", "ammonium", "acyl", "acyloxy", "acylamino", "aminocarbonyl", "alkoxycarbonyl", "ureido", "aryl", "carbamate", "heteroaryl", "sulfinyl", "sulfonyl", "alkoxy", "sulfanyl", "halogen", "carboxy", trihalomethyl, cyano, hydroxy, mercapto, nitro, and the like. Alternatively said substitution could also comprise situations where neighbouring substituents have undergone ring closure, notably when vicinal functional substituents are involved, thus forming, *e.g.*, lactams, lactons, cyclic anhydrides, but also acetals, thioacetals, aminals formed by ring closure for instance in an effort to obtain a protective group.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working

examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims: Scope of the compounds. Owing to the range of many variables, millions of highly substituted methylene amide compounds are embraced.

(2) The nature of the invention: The invention is a highly substituted methylene amide compounds.

(3) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and chemical reactivity (which is affected by determinants such as substituent effects, bonding, molecular geometry, etc) is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(4) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of application's general formula I. Starting on page 28 of the Specification, describes starting materials and methods for synthesis of compounds as mentioned above, but does not describe or list any reagents wherein compounds can

be used to synthesis compounds where Cy and A as listed above. There is limited evidence in the Specification of the example compounds that only covers a small portion of the substituents claimed of formula I. Thus, there is no specific direction or guidance regarding said compounds specifically mentioned in Scope.

The specification provides minimal support for the many claimed variations and substitutents for the synthesis of compounds of Formula I.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 2164.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court *in re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(5) State of the Prior Art: These compounds are substituted methylene amide compounds wherein Cy and A= Cy and A (both phenyl) being substituted by: cyano, halogen,

> **methoxy, hydroxy, phenoxy, -NO_2, trifluoromethyl, Cy is a phenyl or biphenyl being substituted by -SO_2R^3, -CO-$NR^3R^{3'}$ in which $R^{3'}$ is H and R^3 is (C_7-C_{15})alkyl, particularly (C_8-C_{15})alkyl and more particularly a dodecyl group.**

which are well documented in the art. So far as the examiner is aware, no methylene amide substituted methylene amide compounds of general formula I wherein A and Cy are substituted with, as mentioned below, of any kind have been made or used.

> **"Substituted or unsubstituted": Unless otherwise constrained by the definition of the individual substituent, the above set out groups, like "alkyl", "alkenyl", "alkynyl", "aryl" and "heteroaryl" etc. groups can optionally be substituted with from 1 to 5 substituents selected from the group consisting of "C_1-C_6-alkyl", "C_2-C_6-alkenyl", "C_2-C_6-alkynyl", "cycloalkyl", "heterocycloalkyl", "C_1-C_6-alkyl aryl", "C_1-C_6-alkyl heteroaryl", "C_1-C_6-alkyl cycloalkyl", "C_1-C_6-alkyl heterocycloalkyl", "amino", "ammonium", "acyl", "acyloxy", "acylamino", "aminocarbonyl", "alkoxycarbonyl", "ureido", "aryl", "carbamate", "heteroaryl", "sulfinyl", "sulfonyl", "alkoxy", "sulfanyl", "halogen", "carboxy", trihalomethyl, cyano, hydroxy, mercapto, nitro, and the like. Alternatively said substitution could also comprise situations where neighbouring substituents have undergone ring closure, notably when vicinal functional substituents are involved, thus forming, *e.g.*, lactams, lactons, cyclic anhydrides, but also acetals, thioacetals, aminals formed by ring closure for instance in an effort to obtain a protective group.**

It is not trivial to experimentally interchange any and all of the many substituents that exist. As described by F. Zaragoza Dörwald, most organic syntheses fail initially

and chemical research is highly inefficient due to chemists spending most of their time "finding out what went wrong and why". Therefore, most syntheses of organic compounds are labor-intensive and demanding. Additionally, most final synthetic routes to desired organic molecules are usually very different from initially planned routes. A highly skilled chemist can agree that for many successful organic compounds made, many failures are encountered and experimental repetition is common. This also contributes to the burden and unpredictability of the syntheses of said compounds. (see "Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design" 2005 Wiley-VCH Verlag GmbH & Co. KGaA, Wienheim.

(6) Working Examples: Applicant shows several examples in the Specification but no working examples were shown where Cy and A were substituted with the numerous claimed substituent as aforementioned. There are very limited examples of substiuents on the phenyl groups of Cy and A that have been made or used.

(7) Skill of those in the art: The ordinary artisan is highly skilled, e.g. a masters or PhD level chemist.

(8) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

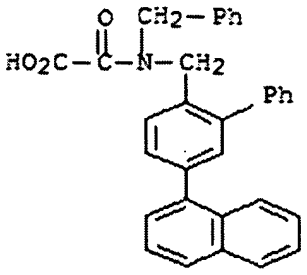
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

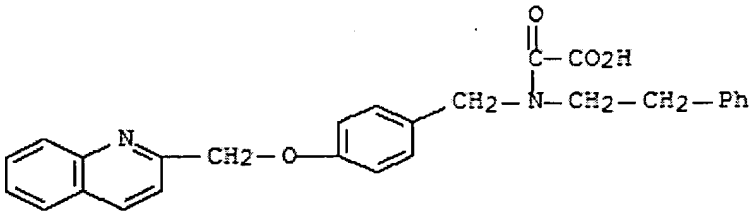
> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 3, 4, 9, 12, 13, 14, 27, 28 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al (US 6,627,767 B2).

Liu discloses compounds of Formula I, wherein R1=CH2Ph, R2a and R2b=H and Cy=phenyl substituted with phenyl (see Example 30, column 31, lines 57-60).



Liu also discloses compounds of Formula I, wherein R1=CH2CH2Ph, R2a and R2b=H and Cy=phenyl substituted with -O-CH2-quinoline (see Example 11, column 26, lines 29-41).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 3, 4, 5, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 27, 28 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al (US 6,627,767 B2).

The instant application claims compounds of Formula I and pharmaceutical compositions thereof wherein R1=C1-C15 alkyl, R2a and R2b=H and Cy=phenyl.

Scope & Content of Prior Art MPEP 2141.01

Liu teaches compounds of Formula I and pharmaceutical compositions thereof wherein R1=lower alkyl, R2a and R2b=H and Cy=phenyl.

Furthermore, the genus of Formula I, column of the reference by Liu teaches R1=cycloalkyl, aryl, heteroaryl, -CH2-A and –CH2-CH2-A wherein A=aryl, heteroaryl; and Cy=aryl, heteroaryl unsubstituted or substituted with alkoxy, aryl, halogen, carboxamidoalkyl, carboxamido, alkoxy, (column 1, lines 41-64, column 2, lines 1-67 and column 3, lines 1-20).

Differences between Prior Art & the Claims MPEP 2141.02

Liu teaches the same aforementioned compounds of Formula I as claimed in the instant application.

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

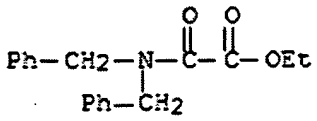
It would be obvious to one of ordinary skill in the art at the time the invention was made to utilize the teachings of Liu to make compounds and pharmaceutical compositions of Formula I in order to treat metabolic disorders mediated by insulin resistance or hyperglycemia such as diabetes type I and II (see column 1, lines 14-39). Thus said, claims are rendered obvious Liu.

Claims 1, 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burrows et al (J. Org. Chem. 1982, 47, 892-893).

The instant application claims compounds of Formula I wherein R1=CH2-phenyl, R2a and R2b=H and Cy=phenyl.

Scope & Content of Prior Art MPEP 2141.01

Burrows disclose compound of Formula I wherein R1=CH2-phenyl, R2a and R2b=H and Cy=phenyl with an 2-oxoacetate at its terminus (see page 893, Scheme I, compound 4).



Differences between Prior Art & the Claims MPEP 2141.02

Burrows differs from the instant application at the terminus position: Burrows' oxoacetate (C(O)CO2Et) versus Applicants' oxoacetic acid (C(O)CO2H).

Prima Facie Obviousness, Rational & Motivation MPEP 2142-2413

It would be obvious to one of ordinary skill in the art at the time the invention was made to saponify (hydrolyze) the oxoacetate of Burrows in order to achieve Applicants' oxoacetic acid compound of Formula I. Thus said, claims are rendered obvious Burrows.

Note: When the compounds of instant application becomes in condition for allowance and Applicant requests for method of treatment claim(s) to be rejoined, an obvious-type double patenting rejection will be made with conflicting US Application 2007/0185118 A1 (10/590,808).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Mabry, PhD whose telephone number is (571) 270-1967. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JM

RITA DESAI
PRIMARY EXAMINER
1/4/08